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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,981	01/20/2004	Mark W. Kroll	A04P1004US01	4011

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
LEE, YUN HAENG NMN	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,981	KROLL ET AL.	
	Examiner	Art Unit	
	Yun H. Lee	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22* is/are allowed.

6)☒ Claim(s) *1-13,15-18 and 21* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6, 8, 10, 11, 14-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilz et al. (US Pat. No. 6,044,295) in view of Marincic et al. (US Pat. No. 5,558,962).

Regarding claim 1, Pilz et al. discloses an implantable pacemaker/defibrillation device comprising:

pacing pulse generation circuitry (7);

defibrillation shock generation circuitry (5, col. 6 lines 1-4);

a first power source (1) to provide power for the pacing pulse generation circuitry; and

a second power source (2) employing lithium manganese dioxide ($LiMnO_2$) (col. 5 line 49) to provide power for the defibrillation shock generation circuitry.

The claim differs from the disclosed invention of Pilz et al. in that the first power source is a polycarbon monofluoride (CF_x) power source. Examiner considers the use of CF_x power sources in implantable medical devices to be conventional and well known in the art with Marincic et al. being but one example. Marincic et al. discloses a highly reliable solid CF_x cathode power source for use in a wide range of electronic devices designed

for surgical implantation into humans or animals (col. 1 lines 9-56). Therefore, it would have been obvious to one of ordinary skill in that art at the time of invention to modify the first power source of Pilz et al. to be a polycarbon monofluoride (CF_x) power source in order to provide a highly reliable power source capable of providing an adequate amount of current and voltage for an extended period of time.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to permanently electrically decouple the second power source of Pilz et al. from the pacing pulse generator to provide power only for the defibrillation shock generation circuitry because Applicant has not disclosed that this decoupling provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the complementary battery configuration of Pilz et al. since the two batteries are normally electrically decoupled until the first power source has insufficient charge to operate the pacing pulse generation circuitry and this does not interfere with the device being used as a prophylactic device. Therefore, it would have been an obvious matter of design choice to modify the device of Pilz et al. to obtain the invention as specified in claim 1.

Regarding claim 2, Pilz et al. discloses the device of claim 1 configured as a prophylactic device for delivering defibrillation shocks in response to a single episode of ventricular fibrillation. The device of Pilz et al. is configured for delivering defibrillation

shocks in response to not only a single episode of ventricular fibrillation, but also multiple episodes of ventricular fibrillation (col. 5 line 58).

Regarding claim 3, Pilz et al. discloses the device of claim 2 configured to be capable of delivering up to six defibrillation shocks in response to the single episode of ventricular fibrillation. In fact, the device of Pilz et al. can deliver more than six defibrillation shocks (col. 5 line 58).

Regarding claim 4, Pilz et al. does not expressly disclose that the individual defibrillation shocks have energies in the range of 10-40 joules. Examiner took Official Notice in a previous Office Action of the fact that it is well known in the art of implantable defibrillators for defibrillation shocks to have energies in the range of 10 to 40 joules in order to expose the patient to the smallest amount of energy possible to minimize discomfort while maintaining a high probability of terminating an arrhythmia with the shock. Since Applicant failed to adequately traverse this Official Notice, it is now taken to be admitted prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the defibrillation shock generation circuitry to provide individual shocks having energies in the range of 10 to 40 joules in order to expose the patient to the smallest amount of energy possible to minimize discomfort while maintaining a high probability of terminating an arrhythmia with each individual shock.

Regarding claim 5, Pilz et al. discloses the implantable device of claim 1 further comprising control circuitry (4) operative to control the pacing pulse generation circuitry and the defibrillation shock generation circuitry and wherein the first power source additionally provides power for the control circuitry (col. 5 lines 65-67).

Regarding claim 6, Pilz et al. discloses the implantable device of claim 1 wherein the defibrillation shock generation circuitry includes a capacitor operative to store charge for a defibrillation shock (col. 6 lines 3-4).

Regarding claim 8, Pilz et al. does not expressly disclose what type of capacitor is used. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the device as taught by Pilz with an aluminum oxide shocking capacitor since it was known in the art that aluminum oxide capacitors are used to provide high energy output in shocking circuitry. In addition, Applicant discloses at page 2, paragraph 4 that the use of aluminum oxide capacitors is well known in the implantable pacemaker/defibrillator art.

Regarding claims 10, 11, 14-16, Pilz et al. does not expressly disclose what combinations of electrodes are coupled for delivering ventricular defibrillation shocks or pacing pulses. Examiner took Official Notice in a previous Office Action of the fact that it is well known in the art to use the various electrode configurations listed here depending on the particular application. Since Applicant failed to adequately traverse

this Official Notice, it is now taken to be admitted prior art. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to have used any of the electrode configurations specified in claims 10, 11, 14 and 15 for the delivery of ventricular defibrillation shocks and pacing pulses in the device of Pilz et al.

Regarding claims 17 and 18, the limitations have been met by the above discussion of claim 1.

Regarding claim 21, Pilz et al. discloses a method for providing pacing and defibrillation therapy using an implantable medical device having pulse generation circuitry and defibrillation shock generation circuitry, comprising the steps of:

providing a first power source (1) electrically coupled to the pulse generation circuitry and a second power source (2) electrically decoupled from the pacing pulse generation circuitry;

upon detecting a need for pacing therapy, selectively delivering power from the first power source to pacing pulse generation circuitry for generating pacing pulses (col. 3 lines 39-40); and

upon detecting a need for ventricular defibrillation therapy, selectively delivering power from the second power source employing lithium manganese dioxide ($LiMnO_2$) to the defibrillation shock generation circuitry for generating shocks for ventricular defibrillation (col. 3 lines 38-39).

Regarding the permanent decoupling of the second power source from the pacing pulse generation circuitry and the employment of polycarbon monofluoride (CF_x) in the first power source, see above discussion of claim 1.

3. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilz et al. (US Pat. No. 6,044,295) in view of Marincic et al. (US Pat. No. 5,558,962) as applied to claim 1 above, and further in view of Norton et al. (US Pat. Appl. Pub. No. 20040243183). Pilz et al. does not expressly disclose what type of capacitor is used. Pilz et al. is also silent regarding reformation of the capacitors. Norton teaches of using a tantalum capacitor (paragraph 29 lines 1-2) which does not require reformation in implantable defibrillators for the advantage of having an extended battery life due to elimination of non-therapeutic charging required by reformation (paragraph 13) and greatly improved efficiency of capacitor charging (paragraph 15). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include non-reformation based defibrillation generation circuitry with a tantalum capacitor in order to extend battery life and greatly improve efficiency of capacitor charging.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilz et al. (US Pat. No. 6,044,295) in view of Marincic et al. (US Pat. No. 5,558,962) as applied to claim 1 above, and further in view of Regna (US Pat. No. 4,796,630). Pilz et al. does not expressly disclose that shunt diodes interconnect the right ventricular tip and ring electrodes and right atrial tip and ring electrodes, respectively. Regna discloses a

cardiac pacemaker that has combined defibrillation and electrosurgery protection (see Regna Abstract). Regna further discloses a protection circuit interposed between a tip 36 and ring 38 electrode including a zener diode, read as a shunt diode 42 (see Regna Fig. 2 and col. 3, lines 1-11). Regna further discloses that such a protection circuit may be utilized with a dual chamber pacemaker and that the shunt diode 42 protects the pacing circuitry from any defibrillation shock energies that may be applied across the heart of the patient (see Regna col. 1, lines 35-52 and col. 3, lines 50-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pilz et al. to include shunt diodes interconnected between the right ventricular tip and ring electrodes and right atrial tip and ring electrodes, respectively in order to provide defibrillation and electrosurgery protection to the pacing pulse generation circuitry.

Allowable Subject Matter

5. Claim 22 is allowed.

6. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments filed 7/31/2006 have been fully considered but they are not persuasive. Applicant's amendment is insufficient to overcome an obviousness

rejection. Applicant gives no criticality to the configuration of having the two power sources permanently decoupled. Applicant fails to give any reason for why the claimed arrangement is advantageous over any other arrangement. No particular purpose or stated problem is solved by ensuring that the two power sources are permanently decoupled.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766

yhl